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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,620	03/24/2004	Jessie L.-S. Au	TNI -2-011	4039
265 7590 04/09/2008 MUELLER AND SMITH, LPA MUELLER-SMITH BUILDING 7700 RIVERS EDGE DRIVE COLUMBUS, OH 43235				
EXAMINER				
ANDERSON, JAMES D				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
04/09/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

<b>Application No.</b> 10/807,620	<b>Applicant(s)</b> AU ET AL.
<b>Examiner</b> JAMES D. ANDERSON	<b>Art Unit</b> 1614

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 06 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  
NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 22, 26-28 and 30-34.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☒ Note the attached *Information Disclosure Statement*(s). (PTO/SB/08) Paper No(s): 3/6/2008

13. ☐ Other: \_\_\_\_\_.

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

/James D Anderson/  
Examiner, Art Unit 1614

Continuation of 11, does NOT place the application in condition for allowance because: Applicants' Arguments/Remarks as well as the 1.132 Declaration of Jessie L.-S Au filed 3/6/2008 have been considered but they fail to persuade the Examiner of an error in his determination that the claims are unpatentable over USP No. 6,855,338 to Dupont. Applicants argue that it is a material error to ignore printed instructions in applying Section 103(a) if there exists any new and unobvious functional relationship between the printed matter and the composition of the kit (citing *In re Ngai*, 35 USPQ2d 1384 (Fed. Cir. 2004)). However, as the Court found in *Ngai*, one is not entitled to a patent on a known product simply by attaching a set of instructions to that product. Such is the case here. Applicants are predicated patentability of their kit on the fact that the printed instructions provide a method of calculating the dose of suramin administered from the kit. This is not seen as providing a functional relationship between the printed matter and the composition of the kit because Dupont teaches that kits comprising suramin for use in treating tumors which may also be administered with one or more other antineoplastic agents. The fact that Applicants discovered that low-dose suramin administered with antineoplastic agents provides an unexpected result rightfully entitles them to such methods of use (see issued USP No. 6,599,912 B1). However, such a finding does not entitle them to patent the claimed compositions comprising printed instructions for administering suramin in combination with an antineoplastic agent.

Regarding the 1.132 Declaration of Jessie L.-S. Au, while this Declaration would be persuasive with respect to methods of administering suramin in combination with an antineoplastic agent or methods of determining the proper dose of suramin to be administered, it is not persuasive with respect to the claimed kits for the reasons of record and as discussed above. The printed matter of the claimed kits is not seen to provide a new and unobvious functional relationship between the printed matter and the composition of the kit. In other words, a kit comprising suramin for use in the treatment of tumors was known in the art. As such, it is not unobvious to provide printed instructions for administering the suramin of the kit.